THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA EX REL. STEPHEN MCMULLEN Relator, vs. ASCENSION HEALTH, SETON CORPORATION (D/B/A BAPTIST HOSPITAL), HICKMAN COMMUNITY HEALTH CARE SERVICES, INC. (D/B/A HICKMAN COMMUNITY HOSPITAL), and MIDDLE TENNESSEE MEDICAL CENTER, INC. Defendants.	)	Case No.3:12-cv-0501 Judge Campbell Magistrate Judge Griffin

RELATOR'S RESPONSE IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

Relator Stephen McMullen respectfully submits this Response in Opposition (the "Response") to the Motion to Dismiss Relator's Amended Complaint for Damages (the "Motion") filed by Defendants Ascension Health, Seton Corporation (d/b/a Baptist Hospital), Hickman Community Health Care Services, Inc. (d/b/a Hickman Community Hospital), and Middle Tennessee Medical Center, Inc. (collectively, "Defendants"). For the reasons set forth more fully below, the Motion should be denied.

I. PRELIMINARY STATEMENT

The "noninvasive vascular diagnostic study," a medical test that has grown in popularity in recent years, forms the crux of this litigation. By taking advantage of "ultrasonic Doppler and physiologic principles," the technique – commonly performed via ultrasound – strives to identify "irregularities in blood flow in arterial and venous systems." (Am. Compl., Ex. A.) Given the

nature and objectives of this procedure, it is generally prescribed for patients comprising an "older population," the majority of whom are eligible for coverage by Medicare insurance. (*Id.* ¶ 38.)

To be sure, the noninvasive vascular diagnostic study (the "NVDS") is on the forefront of medical technology, making its effectiveness contingent upon the training and expertise of those responsible for its administration. To this end, a leading voice for those delivering the service, the Society for Vascular Ultrasound, has taken a firm stand in support of the "certification of all personnel providing noninvasive testing" because the NVDS is "***so*** dependent on the skill and judgment of the personnel performing the service." (Am. Compl., Ex. B at 3 (emphasis added).) Many Medicare intermediaries – including those authorized to assess and pay claims submitted by healthcare providers in Tennessee – have agreed that "[t]he accuracy of [NVDSs] depends on the knowledge, skill, and experience of the technologist and interpreter" (*id.*, Ex. B at 2), and have accordingly promulgated Local Coverage Determinations ("LCD"s) extending Medicare coverage to the procedure ***only*** when it is conducted by (1) "a [p]hysician who is competent in diagnostic studies or under the general supervision of physicians who have demonstrated minimum entry level competency by being credentialed in vascular technology;" (2) "a technician who is certified in vascular technology;" or (3) persons in "facilities with laboratories accredited in vascular technology" (*id.* ¶ 18).

Virtually identical requirements have for years been found in LCDs applicable to Tenneessee Medicare providers, but it has only been since the service of Relator's Amended Complaint upon them that Defendants have adopted policies meant to ensure compliance with the standards. To emphasize, ***now that they have become aware of this lawsuit, Defendants have begun to require that NVDSs carried out at their hospitals be performed by certified***

technicians or under a doctor's care. Before this recent reversal of course, as observed by Relator during his employment with Defendant Ascension Health ("Ascension"), Defendants sought and received Medicare payments for NVDSs that had not occurred in accredited laboratories and had not been administered by or under the supervision of a qualified physician or by a certified technician. Nevertheless, the Medicare claims attributable to Defendants' numerous deficient studies falsely certified that the tests satisfied all applicable guidelines.

As a result of their fraudulent Medicare claims demanding reimbursement for substandard NVDSs performed in Tennessee, Defendants have extracted from the United States government wrongful payments exceeding $1,000,000 per year. (Am Compl. ¶ 28.) Relator has instituted this action under 31 U.S.C. § 3729 in order to recoup those sums.

II. FACTUAL BACKGROUND

Relator is a fully credentialed vascular technologist, and it was in that capacity that he was employed by Ascension to work at Defendant Seton Corporation (d/b/a Baptist Hospital) ("Baptist") from approximately September 2011 through July 2012. (Am. Compl. ¶ 34.) During that period of time, Relator acquired knowledge about Ascension's policies regarding NVDSs, along with the billing procedures attendant to those studies, effective in the company's hospitals throughout Tennessee (that is, all Defendants). (*Id.* ¶¶ 36-37.) More specifically, Relator learned that it was Defendants' practice to bill Medicare for NVDSs notwithstanding that the procedures regularly failed to meet the criteria for reimbursement under the governing LCD.

Medicare only provides coverage for "items or services" that are both "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Because the Secretary of Health and Human Services, through the Centers for Medicare and Medicaid Services (the "CMS"), has yet to issue a National Coverage Determination (a "NCD") encompassing NVDSs, the circumstances in which

Medicare deems the procedure reasonable and necessary are specified by LCDs developed by fiscal intermediaries with jurisdiction over a particular area.[1] 42 U.S.C. §§ 1395h, 1395ff(f)(1)(B), (2)(B). Again, the Amended Complaint alleges that for years the LCDs defining the terms of coverage for NVDSs in Tennessee have approved the tests only when

> (1) performed by persons with appropriate training that have demonstrated minimum entry level competency by being credentialed by a nationally recognized credentialing organization in vascular technology . . ., (2) performed by or under the direct supervision of a physician, or (3) performed in facilities with laboratories accredited in vascular technology.

(Am. Compl. ¶ 19.)

Relator has personal knowledge that Defendants repeatedly, on a daily basis, submitted claims for Medicare payments stemming from NVDS procedures that fell short of the LCD imperatives. (Am. Compl. ¶¶ 29, 37-40, 44-49, 53, 55.) To begin with, Relator was a properly certified vascular technologist, but most of the peers alongside whom he worked were not similarly qualified. (*Id.* ¶ 34.) Indeed, Relator was frequently the ***only*** certified technician on his shift (*id.* ¶ 46), and he knows of shifts staffed exclusively by technicians without certifications (*id.* ¶¶ 47-48). Although non-certified technicians outnumbered their certified counterparts like Relator, Defendants employed no mechanism to assure that a certified technician would tend to patients with Medicare. (*See id.* ¶¶ 44-46.) To the contrary, Relator oftentimes discovered that those waiting for NVDSs were eligible for Medicare, only to later realize that technicians

[1] While subordinate to NCDs, LCDs carry great weight in the Medicare regulatory scheme. *See* 42 C.F.R. § 405.1062(a) (declaring that LCDs are entitled to "substantial deference"). Most significantly for present purposes, the LCD describes when a technique – such as the NVDS – is "reasonable" and "necessary," and thus reimbursable for purposes of Medicare. *See* 42 U.S.C. §§ 1395h, 1395ff(f)(2)(B). As such, Defendants could only obtain payment for an NVDS by certifying (many times falsely) that the test met all the prerequisites set by the governing LCD. (*See* Am. Compl., Ex. B at 2 ("Medicare carriers and [i]ntermediaries . . . define what is 'medically necessary' . . . by . . . a Local Coverage Determination.").)

without certifications had handled the individuals' exams. (*Id.* ¶¶ 45-46.) Relator found out that this situation repeated itself at all Ascension hospitals in Tennessee, none of which qualifies as an accredited vascular laboratory. (*Id.* ¶¶ 36-37.) Because Defendants do not assign physicians to supervise NVDSs – either directly or generally[2] (*id.* ¶¶ 34, 37) – it was inevitable that this routine would produce countless Medicare recipients who received NVDSs that did not live up to the LCD benchmark.

Relator's empirical observations were borne out by a review of Defendants' records. Relator was responsible for Quality Control at Baptist between June 15, 2011 and November 19, 2011, and in that role he confirmed that a full 42% of the hospital's NVDSs did not pass muster under the controlling LCD. (Am. Compl. ¶¶ 39, 41.) That is telling, especially given the maturity of the population designated to receive NVDSs. (*Cf. id.* ¶ 38.) Defendants' shoddy and reckless method of billing, with which Relator was intimately familiar (*see* Am. Compl. ¶ 49), made the submission of false claims unavoidable.

At Ascension hospitals such as Baptist, the technicians who performed NVDSs were responsible for supplying necessary information in the bills sent to Medicare. (Am. Compl. ¶ 49.) Significantly, the software used by technicians to enter data considered pertinent did not inquire whether a certified technician performed the NVDS. (*Id.*) As a consequence, Defendants had no way to ascertain whether the procedure qualified for Medicare coverage. In the end, this did not matter to Defendants: They forwarded the claims to Medicare, even if they did not comply with the LCD.

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[2] Defendants make much of the fact that the Amended Complaint variously refers to the "direct" and "general" supervision of a physician. (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 11 n.8.) To be clear, the pleading explicitly states that ***neither*** type of oversight occurred at Defendants' hospitals (Am. Compl. ¶¶ 34, 37), rendering specious Defendants' argument in this vein.

The preceding paragraphs demonstrate that Defendants submitted false claims in order to receive Medicare payments. That being so, Defendants' Motion to Dismiss should be denied.

III. ARGUMENT

A. Applicable Standard Of Law

In reviewing a motion to dismiss for failure to state a claim, the court must accept a complaint's allegations as true, while also drawing all reasonable inferences in favor of the plaintiff. *DIRECTTV, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). When applying Rule 12(b)(6) of the Federal Rules of Civil Procedure, it is sufficient if a plaintiff pleads "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Above all else, the complaint must be construed in the light most favorable to the party opposing the motion to dismiss. *Davis H. Elliot Co. v. Carribbean Utils. Co.*, 513 F.2d 1176, 1182 (6th Cir. 1975).

Although opposing counsel relies heavily upon the heightened pleading standard set out in Rule 9(b) of the Federal Rules of Civil Procedure, which applies to lawsuits under the False Claims Act, they have failed to mention an important exception to the strict pleading standard. Importantly, a relaxed application of Rule 9(b) holds sway "'in circumstances where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator.'" *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 472 (6th Cir. 2011) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 n.12 (6th Cir. 2007)). The United States Court of Appeals for the Sixth Circuit in *Chesbrough* further elaborated that the

Rule 9(b) demands "may be relaxed when, even though the relator is unable to produce an actual billing or invoice, he or she has [pleaded] facts which support a *strong inference* that a claim was submitted." *Id.* at 471 (emphasis in original).

Lastly, there is no presentment requirement for either 42 § 3729(a)(2) or (a)(3). *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671, 673 (2008). Only subsection 3729(a)(1) requires presentment to the government.

B. Relator Has Sufficiently Pleaded A Claim Against Baptist

Initially enacted as a response to wholesale fraud perpetrated upon the union government during the Civil War, the False Claims Act (the "FCA") was "substantially amended" in 1986 "to combat fraud in the fields of defense and *health care*." *Mikes v. Straus*, 274 F.3d 687, 692 (2d Cir. 2001) (emphasis added). Liability under the statute arises whenever a defendant "(1) makes a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Id.* at 695. Because the Amended Complaint alleges with the requisite degree of specificity that Baptist engaged in conduct implicating each of these elements, Relator has stated a viable claim against the hospital for violation of the FCA.

1. The Amended Complaint Alleges With Particularity That Baptist Engaged In A Fraudulent Scheme

It is a defendant's attempt to "extract from the government money the government otherwise would not have paid," *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011) (quotation omitted), that lies at the heart of any FCA violation. Recognizing the ingenuity of those determined to commit fraud, courts have remained mindful that the methods used to achieve this "extract[ion]" can take any number of forms. *See, e.g., United States ex rel. Conner v. Salina Reg'l Health Ctr, Inc.*, 543 F.3d 1211, 1217-18 (10th Cir. 2008). Along with claims for

payment that are "factually false" – insofar as they desire reimbursement for something inaccurately described or not actually provided – an FCA violation can also spring from a "legally false" certification. *Id.* at 1217. "Legally false" claims can themselves be of either the "express" or "implied" variety, *id.* at 1217-18, but it is only the latter type that is currently at issue. When it submitted claims for payment tied to NVDSs performed by non-certified technicians, Baptist falsely represented that it had "compl[ied] with the [LCD] on which payment [was] conditioned." *Chesbrough*, 655 F.3d at 468 (quotation omitted). The Amended Complaint makes this much clear.[3]

In the case of Baptist, Defendants curiously assert that Relator neither "allege[s] the violation of any regulatory standard" nor that "compliance with such a standard was a condition for payment." (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 11.) By taking such a position, it is as if Defendants have never read the Amended Complaint, for Relator repeatedly makes both of these allegations. In the pleading's second paragraph, for instance, Relator maintains that Defendants have used "non-accredited and/or non-certified technicians to perform [NVDSs]" despite the fact that "***Medicare reimbursement criteria require***[] that for [NVDSs] to be compensable, they must be performed by a physician or technician certified in vascular technology or supervised by a physician credentialed in vascular technology or performed by an

[3] Because the value of NVDSs is "***so***" dependent upon the "skill and judgment" of the technician conducting the test (Am. Compl., Ex. B at 3 (emphasis added), Relator submits that the procedures underlying Defendants' fraudulent Medicare claims were essentially worthless (*see id.*, Ex. B at 2 ("The accuracy of [NVDSs] depends on the knowledge, skill, and experience of the technologist and interpreter.")). As a result, even in the absence of any express or implied "certification" by Defendants, Relator has stated a justiciable claim under the FCA. *See Chesbrough*, 655 F.3d at 468 ("A test known to be of 'no medical value,' that is billed to the government would constitute a claim for 'worthless services' . . . ."); *Mikes*, 274 F.3d at 703 ("[A] worthless services claim is a distinct claim under the [FCA]."); *cf. United Sates ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006) ("So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake.").

accredited laboratory." (Am. Compl. ¶ 2.) Over and over again during the length of the Amended Complaint, Relator contends that Medicare regulations require as a condition of payment that NVDSs occur in an accredited laboratory, under the supervision of a physician, or at the hands of a certified technician (*e.g., id.* ¶¶ 2, 18-19), yet Defendants (including Baptist) failed to satisfy these conditions (*e.g., id.* ¶¶ 2, 26-27, 34, 36-37, 39-42, 46, 50). Defendants' insistence to the contrary is meritless.

The Amended Complaint describes with particularity the fraudulent scheme pursued by Baptist and the other Defendants. Defendants urge dismissal by closing their eyes to this certainty, but those arguments should be rejected.

2. The Amended Complaint Alleges That LCDs Requiring The Certification Of Technicians Applied To Baptist

The Amended Complaint identifies LCDs prescribing Baptist's conduct during the time period relevant to this action. (Am. Compl. ¶¶ 17-19.) Baptist effectively concedes that one of the LCDs has applied to its Medicare claims for some months covered by the Amended Complaint (*see* Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 14 (acknowledging that a controlling LCD from Cahaba has been in place since August 2012)), but it otherwise denies that it was subject to the regulations in question. This general denial furnishes no cause for dismissal.

The Medicare rules and regulations have been characterized as "beasts unto themselves." *United States ex rel. Parato v. Unadilla Health Care Ctr., Inc.*, No. 5:07-CV-76 (HL), 2010 WL 146877, at *7 (M.D. Ga. Jan. 11, 2010). Relator has singled out in the Amended Complaint the LCDs with authoritative force in Tennessee over the pertinent time frame. (Am. Compl. ¶¶ 17-19.) If Baptist truly denies that those LCDs had any bearing upon it save for certain discrete

periods, that is a matter best left for summary judgment,[4] particularly when Baptist allows that at least one of the LCDs did apply to it for some of the time at issue. At this motion to dismiss stage, it suffices that the Amended Complaint pinpoints allegedly controlling LCDs,[5] none of which permit Medicare payment for NVDSs completed at a non-accredited laboratory by a non-certified technician. By further averring that Baptist frequently certified falsely that it honored those specifications, the Amended Complaint makes out a valid cause of action under the FCA. The Motion to Dismiss should be denied.

3. The Amended Complaint Adequately Describes, Based On Relator's Personal Knowledge, Baptist's Presentment Of Multiple False Claims

Defendants are correct that the Sixth Circuit interprets Rule 9(b) to mandate the "pleading [of] an actual false claim with particularity" in a complaint bringing a cause of action under the FCA. *Bledsoe*, 501 F.3d at 504. Defendants conveniently ignore, however, that the

[4] On this score, Relator notes that it would be entirely improper to convert the Motion into a request for summary judgment. *See* Fed. R. Civ. P. 12(d). "[I]t is 'serious error' for a district court to convert [a motion to dismiss] *sua sponte* to a summary judgment motion without notice to the parties and without further discovery." *Ball v. Union Carbide Corp.*, 385 F.3d 713, 719 (6th Cir. 2004) (quoting *Helwig v. Vencor, Inc.*, 251 F.3d 540, 552 (6th Cir. 2001) (en banc)). Should Baptist seriously believe that it was authorized to acquire reimbursement for NVDSs performed by unsupervised, and non-certified, technicians, Relator is undoubtedly entitled to conduct discovery on the "beasts" doubling as Medicare rules and regulations. *See Parato*, 2010 WL 146877, at *7. With regard to Baptist's request that the Court take judicial notice of the status occupied by certain entities, Relator disagrees that such a circumstance is either "generally known" within this Court's geographic jurisdiction or "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). In any event, whether and when a particular organization served as a Medicare intermediary says nothing about the substance of particular LCDs to which Baptist was beholden.

[5] Dismissal is also warranted, according to Baptist, because LCDs do not have "the force and effect of law." (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 14.) Whether or not this is true, it is completely beside the point. The fact remains that LCDs delimit the conditions under which an item or service is "reasonable" and "necessary," 42 U.S.C. §§ 1395h, 1395ff(f)(2)(B), and Baptist was only able to obtain payment by falsifying its claims so that they caused "the government to make . . . payment[s] which it would not otherwise have made, *Conner*, 543 F.3d 1219.

circuit court also recognizes at least one set of circumstances that justifies "relaxation" of this Rule 9(b) requirement. Namely, "a court may 'relax' the requirement of Rule 9(b) in circumstances where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator." *Chesbrough*, 655 F.3d at 470 (quoting *Bledsoe*, 501 F.3d at 504 n.12). If ever there were a case for application of the exception, this is it.

First of all, it cannot be gainsaid that false claims "in all likelihood exist" here. The factual summary in Section II of this Response reveals that NVDSs are generally prescribed for a clientele containing a disproportionate number of Medicare recipients (Am. Compl. ¶ 38), and Defendants took no steps to make sure that none but certified technicians would conduct the exams for Medicare patients (*id.* ¶ 44-46). As a consequence, during his tenure coordinating Quality Control at Baptist, Relator confirmed that a full 42% of NVDSs were deficient under the governing LCD. (*Id.* ¶¶ 39, 41.) What is more, Relator often observed that technicians without certifications would assume responsibility for the NVDSs of Medicare eligible patients (*id.* ¶¶ 45-46), and he knew of shifts staffed solely by non-certified technicians (*id.* ¶¶ 47-48).

In these circumstances, it is putting it mildly to propose that false claims "in all likelihood exist." *Chesbrough*, 655 F.3d at 470. This is all the more apparent given Relator's knowledge of Defendants' billing system. To repeat, Defendants relied on Relator and other technicians to supply the information to be sent to carriers like Medicare. (Am. Compl. ¶ 49.) It is therefore a paramount consideration that Defendants' billing software, used by those technicians, never inquired whether the person performing the NVDS was certified. (*See id.*) It follows, then, that Defendants sent the bills seeking payment from Medicare irrespective of a technician's certification.

The Sixth Circuit has suggested that cases like this – in which a Relator has knowledge of a defendant's billing procedures – cry for application of the exception allowing relaxation of Rule 9(b). *See Chesbrough*, 655 F.3d at 471 (reporting that exception has been applied in one case involving "a former billing department employee," and another with a relator possessing "specialized knowledge of defendant's billing practices"). The underlying facts, as set forth above, create a "strong inference" that Baptist submitted false claims to secure Medicare payments. *See id.* (providing that such a "strong inference" justifies application of the exception). In the final analysis, because false claims "in all likelihood exist," but are unavailable through no fault of Relator, this Court should conclude that the Amended Complaint alleges Baptist's presentment of false claims consistent with a "relaxed" Rule 9(b) requirement.

4. The Amended Complaint Satisfactorily Alleges Baptist's Knowledge Of Its Claims' Falsity

"[I]nsofar as a *qui tam* action is concerned with [a defendant's] 'knowledge,' this element does not need to be pled with particularity." *United States ex re. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496, 505 (6th Cir. 2008); *see also* Fed. R. Civ. P. 9(b) ("[K]knowledge . . . may be alleged generally."). Baptist takes issue with the operative allegations concerning its "knowledge" of the presentment of false Medicare claims, but the Amended Complaint manifestly puts it on "notice" that Relator is declaring just that. *See Bledsoe*, 501 F.3d at 503 ("Rule 8 is commonly understood to embody a regime of 'notice pleading' . . . .").[6] Furthermore, the paragraphs in the Amended Complaint directly addressing knowledge (Am. Compl. ¶¶ 57-59) mirror the allegations deemed acceptable by the Sixth Circuit in *Snapp, Inc.*

[6] Moreover, because pertinent LCDs and industry literature – as summarized in the Amended Complaint – addressed the situation regarding the certification of technicians performing NVDSs (Am. Compl. ¶¶ 17-20), there can be little doubt that the relevant allegations satisfactorily assert Defendants' knowledge under any standard.

See Snapp, Inc., 532 F.3d at 505 n.7 (approving allegation that defendant "knowingly or recklessly submit[ed] to the United States claims that [defendant] knew were false and/or otherwise ineligible for payment").

The Amended Complaint appropriately pleads Baptist's knowledge that the claims it submitted were false, under the standards of Rule 8. The Motion to Dismiss should be denied.

C. Relator Has Sufficiently Pleaded Claims Against Hickman and Middle Tennessee

Defendants argue that Relator fails to plead plausible claims against Defendants Hickman Community Health Care Services, Inc. (d/b/a Hickman Community Hospital) ("Hickman") and Middle Tennessee Medical Center, Inc. ("Middle Tennessee"). Although Relator was employed by Ascension to work at Baptist, through his position he acquired personal knowledge that Hickman and Middle Tennessee followed Ascension's policies and engaged in the same unlawful Medicare practices as Baptist.

Defendants cite *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873 (6th Cir. 2006), in support of their argument that Relator's allegations do not meet the requirements of Rule 9(b). (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 20.) In *Sanderson*, the relator's complaint was dismissed because it did not refer to a specific fraudulent claim filed with the government and did not detail who filed the claim or when it was filed. *Sanderson*, 447 F.3d at 875. This dispute is distinguishable from *Sanderson*, however, because the Amended Complaint qualifies for relaxation of the Rule 9(b) standard when it comes to the pleading of a false claim, *see* Section III.B.3., *supra*, and Relator alleged that Hickman and Middleton Tennessee have filed fraudulent reports "since at least 2008 and possibly since 2002" (Am. Compl. ¶ 2).

Relator states that since at least 2008, Hickman and Middle Tennessee have presented false claims to Medicare for NVDSs which were deficient under the applicable LCDs. (Am.

Compl. ¶¶ 19, 26.) Relator also alleges that neither Hickman nor Middle Tennessee have (1) physicians who are credentialed in NCDSs or (2) laboratories accredited in vascular technology, and both Hickman and Middle Tennessee use non-certified technicians to perform NVDSs, which are geared toward elderly patients. (*Id.* ¶ 37.) Relator alleges that Defendants were engaging in the fraudulent conduct to collect reimbursement from Medicare and enhance their revenue streams. (*Id.* ¶ 2.) As a result of this fraudulent conduct, the United States government suffered damage. (*Id.* ¶ 62.)

Relator has alleged the particulars of the false claims consistent with a "relaxed" Rule 9(b) standard, "the fraudulent scheme," the "fraudulent intent of the [D]efendants," and the injury resulting from the fraud. *Bledsoe*, 501 F.3d at 504. Relator has pled a fraudulent scheme by Defendants and the Motion should be denied.

D. Relator Has Sufficiently Pleaded An FCA Violation by Ascension

Where a relator has alleged that a parent company was directly involved and asserted control, the parent is "liable for having caused [its] subsidiaries to engage in the pervasive and systematic submission of claims in violation of the . . . Medicare Anti-Fraud & Abuse Act," and dismissal is unwarranted. *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1038 (S.D. Tex. 1998).

Defendants argue that Relator's Amended Complaint fails to assert any claim against Ascension as a parent corporation of Baptist, Hickman, and Middle Tennessee and that Relator alleges no facts to connect Ascension to the false Medicare claims submitted by those other Defendants. (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 21-22.) But Relator alleges that Ascension is the *controlling* entity of Baptist, Hickman, and Middle Tennessee. (Am. Compl. ¶¶ 2, 30.) Relator further alleges that Ascension "handles numerous aspects of the

hospital and employees, including all human resources issues, updates and benefits." (*Id.*) Relator alleges that he accessed all his employee information and issues through the Ascension website (*id.* ¶ 31), and as the owner/operator and employer, Ascension handles all employee information, issues, and human resources. Relator also alleges he was paid by Ascension. (*Id.* ¶ 32.) Relator alleges that "Defendants have presented false claims to Medicare for [NVDSs]" and that "Defendant[s] ha[ve] been compensated by Medicare for these non-compensable services." (*Id.* ¶ 2.) Relator has pled sufficient facts to demonstrate that Ascension, by controlling and operating Baptist, Hickman, and Middle Tennessee, played a role in Medicare fraud, and should therefore be liable for having caused its subsidiaries to engage in Medicare fraud.

E. The Amended Complaint Satisfactorily Identifies False Records Made By Defendants Under the Relaxed Application Of Federal Rule 9(B)

This Response has already demonstrated that a relaxed application of Rule 9(b) is to be applied "in circumstances where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator." *Chesbrough*, 655 F.3d at 472 (quotation omitted). Under the relaxed application of Federal Rule 9(b), the Amended Complaint sufficiently identifies the false claims made by the Defendants. By the Relator having first-hand observed the violations of the LCD concerning NVDSs, and having first-hand observed the procedure performed by non-credentialed technicians, all of which he was privy to while employed by Ascension and working at Baptist, Relator has personal knowledge as to the time, place, and content of the alleged false claims. Relator also has personal knowledge as to the manner in which the false statements were to be submitted to the government, as a result of having personally entered and observed the patient data and procedure codes into Defendants' computer system used to track treatment and billing. Relator observed, first hand, in his position

at an Ascension hospital, the violations concerning Defendants' non-compliance with the LCDs at issue in this case. Relator witnessed what was essentially the non-compensable services in the patient data records on the Ascension computer system. Relator was also able to see when each NVDS was performed, who performed the service (*i.e.*, non-credentialed technicians known personally to Relator) as well as the Ascension facility at which it was performed. More importantly, Relator could see that a majority of the facilities' NVDSs were performed on Medicare patients. Relator's allegations are further based on his 20 years of personal and professional experience as a Registered Vascular Technologist ("RVT"), credentialed and accredited by the American Registry of Diagnostic Medical Sonographers. Through his experience Relator is fully aware of what the LCD requires, and the significance of the patient data entered in connection with these procedures, and knows from personal knowledge and observation that the procedures were submitted for billing the same as all the other procedures performed by the technicians, whether credentialed or not.

Relator does not state that on a particular date, for this specific Medicare patient, at this particular time of day, the non-certified technicians performed the ultrasound in violation of the LCD; that is not, however, the pleading standard. Consistent with the required pleading standard, the Relator does state that he observed, first-hand, the Defendants' use of non-certified technicians to perform the ultrasound procedures in violation of the LCD, and that he not only personally observed such occurrences on multiple occasions, but that he also did review, first-hand, the computer system that contained the Medicare patient data, and that the data indicated the standard billing for the procedures. That information is sufficiently detailed to inform Defendants of the fraud alleged. Because Relator has pleaded facts which support a *strong*

inference that a claim was submitted, Defendants' Motion should be denied. *Chesbrough*, 655 F.3d at 471.

Furthermore, there is no presentment requirement in either 42 U.S.C. § 3729(a)(2) or (a)(3). *Allison Engine Co.*, 553 U.S. at 671, 673. The court in *Allison* stated that only subsection 3729(a)(1) requires presentment to the government. In the instant case, Relator saw the patient data in the Baptist computer system, which are for billing purposes sent to Ascension, the parent company. Relator knows that the government contracts for third-party processing of the Medicare claims and enforcement of the LCDs, and did so at the time at issue in the Amended Complaint. Although Relator does have his hand in Baptist's transmission of Medicare claims to the government, Relator did observe and can testify to his observation and knowledge concerning Baptist's submission to Ascension the patient data for billing purposes and ultimately payment by the government. Relator knows, again from his own personal, first-hand experience at Baptist, that the ultrasound procedures performed on Medicare patients were not free, that they were required to submit the patients' data for billing purposes, and that Baptist was often not in compliance with the LCD for the ultrasounds performed on the Medicare patients.

Although Relator cannot presently supply all of the specific details required by a strict interpretation of Rule 9(b), any lack of specificity does not warrant dismissal, as the Amended Complaint still comports with a "relaxed" pleading standard. Furthermore, the lack of information is not attributable to the Relator's conduct. Indeed, the conduct alleged by Relator was not exactly discussed openly and was, arguably, intentionally concealed so as to prevent detection. In this case, Relator was able to piece together the Defendants' scheme as a result of his personal observations and first-hand experiences. Moreover, the facts pleaded in the Amended Complaint support a *strong inference*of the submission of fraudulent claims.

Therefore, Relator sufficiently satisfies the 9(b) pleading standard, wherein the Amended Complaint does substantially identify false records made by the Defendants, thereby enabling Relator to pursue a cause of action under Section 3729(a)(2) and (a)(3).

F. The Amended Complaint Identifies The Elements Of A Conspiracy By Asserting That Ascension Maintains Control Over All Subsidiary Facilities And Billing Practices

Section 3729(a)(3) of the FCA, which makes any person liable who "conspires to defraud the government by getting a false or fraudulent claim allowed or paid," *does not require* the Relator to show that the conspirators intended the false record or statement to be presented directly to the government. *Allison Engine Co.*, 553 U.S. at 673. The United States Supreme Court's interpretation of this language is similar to the interpretation of the language in § 3729(a)(2). *See id.* at 671. It is not necessary to show that the conspirators intended the false record or statement to be presented directly to the Government. *Id.* at 673. Still, one must establish that Defendants agreed that the false record or statement would have a material effect on the government's decision to pay the false or fraudulent claim. *Id.*

In the Amended Complaint, Relator establishes that the NVDSs were performed in violation of the Medicare reimbursement criteria, as well as entered into the Baptist/Ascension computer systems with the intent that they be presented to the government for payment. Although Relator is unable to produce actual fraudulent submissions that were directly made to the government, the Amended Complaint sufficiently establishes that the hospital Defendants were entering fraudulent services into the computer system for billing purposes, and then submitting those claims to their parent company, Ascension. Ascension was then the entity who would coordinate and establish standards for presentation of claims to the government for payment. Due to the convoluted billing process used by Ascension and its subsidiaries, Relator,

who worked at a subsidiary facility, is unable to identify, by Medicare number or invoice number, the fraudulent bills presented to the government for payment. However, there is no question the claims were submitted for payment.

The Amended Complaint satisfies 42 § 3729(a)(3), which only requires Relator to establish that Defendants agreed that the false record or statement would have a material effect on the government's decision to pay the false or fraudulent claim. *Allison Engine Co.*, 553 U.S. at 673. In the Amended Complaint, Relator has established that the hospital subsidiaries willingly shared fraudulent claims with their parent company, Ascension. By exposing Defendants' billing scheme, Relator has sufficiently pled conspiracy and therefore can pursue a cause of action under § 3729(a)(3).

G. The Amended Complaint Should Not Be Dismissed With Prejudice

Defendants argue that the Amended Complaint should be dismissed with prejudice because any further amendment would be futile. Defendants' one paragraph argument rests solely on the proposition that the Amended Complaint was filed in response to Defendants' initial motion to dismiss. Thus, as Defendants see it, Relator has had his "one chance to Amend." (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 25.)

As a preliminary matter, Relator was well within his rights to file an amended complaint in response to the motion to dismiss. Rule 15(a)(1)(B) of the Federal Rules of Civil Procedure allows a plaintiff to file an amended complaint as a matter of course within 21 days after service of a Rule 12(b) motion to dismiss. Nowhere in Rule 15 (or any other rule, for that matter) does it state that a plaintiff is precluded from filing any further amendments should his amended complaint be dismissed. In other words, no rule or law directs that if an amended complaint filed

pursuant to Rule 15(a)(1)(B) is to be dismissed, it must be dismissed with prejudice with no further opportunity to amend.

Defendants cite *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 644 (6th Cir. 2003), for the notion that a plaintiff has only one chance to amend a complaint. (Mem. Law Supp. Defs.' Mot. Dismiss Am. Compl. 25.) *Bledsoe* does not support Defendants' assertion.

The Sixth Circuit in *Bledsoe* stated, "[W]here a more carefully drafted complaint might state a claim, a plaintiff must be given *at least one chance* to amend the complaint before the district court dismisses the action with prejudice." *Bledsoe*, 342 F.3d at 644. Giving a plaintiff "at least one chance" is entirely different from Defendants' position that a plaintiff *only* gets one chance.

In fact, the court in *Bledsoe* reversed the trial court's dismissal of the amended complaint and remanded the case to the district court "to allow [the relator] to comply with Rule 9(b) by amending his amended complaint." *Bledsoe*, 342 F.3d at 645.

Second, Defendants cite to no facts to support their argument. Defendants purely speculate that an order of dismissal would be of such a nature that no further amendment could cure any perceived shortcomings. Defendants have wholly failed to direct the Court to any particular deficiency that is incapable of being cured. Put simply, Defendants' futility argument is a naked assertion not grounded in or supported by fact or law.

III. CONCLUSION

Thanks to this lawsuit, Defendants have recently changed their policies so that only certified technicians may perform NVDSs. It is good that they are no longer defrauding the

government, but it is too little, too late. Relator has stated valid claims against all Defendants under the FCA. The Motion should be denied.

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Respectfully submitted,

/s/ Thomas P. Thrash
Thomas P. Thrash (AR #80147)
Marcus N. Bozeman (TN #19982)
THRASH LAW FIRM, P.A.
1101 Garland Street
Little Rock, AR 72201
Ph: (501) 374-1058
Fax: (501) 374-2222

/s/ Russell A. Wood
Russell A. Wood, Esq. (TN #23102)
WOOD LAW FIRM, P.A.
501 East 4th Street, Ste. #4
Russellville, AR 72801
Ph: (479) 967-9663
Fax: (479) 967-9664

Brian K. Herrington
John W. "Don" Barrett
DON BARRETT, P.A.
404 Court Square North
P.O. Box 927
Lexington, MS 39095
Ph: (662) 834-9168
Fax: (662) 834-2628

Robert A. Clifford
Shannon M. McNulty
CLIFFORD LAW OFFICES
120 N. LaSalle St., Suite 3100
Chicago, IL 60602
Ph: (312) 899-9090
Fax: (312) 251-1160

Attorneys for Relator

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served upon the following counsel of record by the manner indicated this twentieth day of September, 2013.

John-David H. Thomas
Office of the United States Attorney
110 Ninth Avenue, S -- Suite A961
Nashville, TN 37203-3870
(615) 736-5151
Fax: (615) 736-5323
Email: john-david.thomas@usdoj.gov
(VIA ECF)

Counsel for the United States of America

Gregory M. Luce
Mava P. Florence
James C. Buck
SKADDEN, ARPS, SLATE, MEAGHER & FLIM LLP
1440 New York Avenue, N.W.
Washington, DC 20005
(201) 371-7000
(VIA ECF)

Thor Y. Urness
BRADLEY ARANT BOULT CUMMINGS LLP
1600 Division Street
Suite 700
Nashville, Tennessee 37203-0025
(615) 244-2582
(VIA ECF)

Counsel for Defendants

/s/ Thomas P. Thrash